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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,433	11/20/2001	David A. Zarling	A-64580-5/RFT/NBC	4240

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EXAMINER

KAUSHAL, SUMESH

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 06/10/2004

ase find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/990,433

**Applicant(s)**

ZARLING ET AL.

**Examiner**

Sumesh Kaushal Ph.D.

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 49-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 49-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/16/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

*Applicant's response filed on 03/16/04 has been acknowledged.*

*Claims 49-54 are pending and are examined in this office action.*

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**.*

*The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.*

**Claim Rejections - 35 USC § 102**

Claims 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Radding et al (US 4,888,274, 1989 ref of record) for the same reasons of record as set forth in the office action mailed on 10/16/03.

The instant claims are drawn to a composition comprising a plasmid, at least two single-stranded targeting polynucleotides (as claimed) and at least one recombinase. The claims are further drawn to composition wherein the targeting polynucleotides are biotinylated. In addition the claims are drawn to a method of contacting a plasmid with a recombinase and at least two single stranded-targeting polynucleotides.

Radding teaches a composition for homologous targeting comprising single-stranded DNA probes, a recombinase and a double stranded target DNA (fig-1, col.4 line 52). The cited art teaches making of single-stranded polynucleotides from dsDNA sequences (col.5, line 49-52). The cited art further teaches the making of single-stranded polynucleotides probes labeled with biotin (col. 6, lines 5-38; col.21, line 21).

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The cited art further teaches that single-stranded polynucleotides probe is homologous to target substrate DNA (col. 17 example-I and II). The cited art further teaches contacting a plasmid with recombinase and at least two single stranded targeting polynucleotides sequences in the presence of recombinase (col.7 line 35; col.9 line 39, col.18 line.1). In addition the cited art teaches the purification of target polynucleotides sequences using streptavidin-biotin chromatography (col.22 example-VIII). Thus the cited art clearly anticipate the instant invention.

### ***Response to arguments***

The applicant argues that Radding does not teach the invention as claimed, since the teaching in the cited reference of record refers to one probe or plurality of same probe. The applicant argues that cited art does not teach two single stranded probes that are substantially complementary to each other. The applicant argues that Radding does not anticipate the claimed subject matter (response, page 6).

However, applicant's arguments are found NOT persuasive. Given the broadest reasonable interpretation the cited art of record clearly anticipate the invention as claimed. As stated in the earlier office action Radding teaches a composition for homologous targeting comprising single-stranded DNA probes, a recombinase and a double stranded target DNA (fig-1, col.4 line 52). The cited art teaches that single stranded DNA is derived from a duplex cloning vector, such as plasmid, phage or cosmid vectors, which contains a region of homology with the target DNA. The cited art further teaches that to obtain the cloned probe, a cloning vector containing the probe is digested with selected restriction enzyme(s), to form one or more linear vector fragments (col. 5, lines 12-30). Since the cited art teaches making of single stranded DNA from a cloning vector, the single stranded composition disclosed in the cited art of record inherently encompasses complementary strands of a double stranded DNA. Thus the cited art clearly anticipate the invention as claimed.

### ***Conclusion***

No claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sumesh Kaushal  
Examiner GAU 1636

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
